SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health, Alaris® Products®

SAFETY MALE LUER

JAN 12 2006

SUBMITTER INFORMATION

A.	Company Name:	Cardinal Health, Alaris® Products
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2733
C.	Company Phone: Company Fax:	(858) 458-7830 (858) 458-6114
D.	Contact Person:	Stacy L. Lewis Sr. Regulatory Affairs Specialist Cardinal Health, Alaris® Products
E.	Date Summary Prepared:	October 25, 2005

DEVICE IDENTIFICATION

A.	Generic Device Name:	Intravascular Administration Set
B.	Trade/Proprietary Name:	Alaris® Safety Male Luer
C.	Classification:	Class II
D.	Product Code:	FPA, Intravascular Administration Set

DEVICE DESCRIPTION

The SML is a sealed male luer. The SML is designed to promote safe handling of fluids and medications, particularly hazardous or cytotoxic drugs. Leakage of drug into the environments is effectively avoided during all phases of drug handling when the SML is used in conjunction with the SmartSite® Needle Free Valve port: the preparation of the drug, the administration of the drug to the patient, and waste handling.

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DEVICE DESCRIPTION (Continued)

The SML is a passive device – it requires no cap and automatically seals upon disconnection. An optional female cap will be provided for transport and an optional priming cap will be provided to allow the user to prime as necessary.

The Safety Male Luer (SML) is a unique male luer connector that is intended to be used with the currently marketed SmartSite® Needle Free Valve port and standard open female luers. The SML design includes an internal mechanism that causes the luer to seal when disconnected. In doing so, it prevents the dripping or accidental spillage of fluids that otherwise occur when using a standard, unsealed male luer. Thus, the SML is intended to provide leak-free handling of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products. Furthermore, the SML reduces environmental surface contamination of the work surface when used to reconstitute, dispense/transfer, administer, and dispose of hazardous or non-hazardous fluids when used in conjunction with SmarSite® Needle-Free Valve port.

SUBSTANTIAL EQUIVALENCE

The Cardinal Health, Alaris® Products Safety Male Luer is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No:	Date Cleared
PhaSeal System	Carmel Pharma AB	K972527	9/18/97
CML 1000	ICU Medical, Inc.	K051437	8/3/05

INTENDED USE

The Safety Male Luer is intended to provide leak-free handling of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, during all three phases of drug handling when the SML is used in conjunction with the SmartSite®

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INTENDED USE (Continued)

Needle Free Valve port: the preparation of the drug, the administration of the drug to the patient, and waste handling.. The Safety Male Luer is intended to reduce environmental surface contamination of the work area.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Alaris® Safety Male Luer and the predicate devices has been performed. The results of this comparison demonstrate that the Alaris® Safety Male Luer is equivalent to the marketed predicate devices in technological characteristics.

PERFORMANCE DATA

The performance data indicate that the Alaris® Safety Male Luer meets specified requirements and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 2 2006

Ms. Stacy L. Lewis
Senior Regulatory Affairs Specialist
Cardinal Health, Alaris® Products
10221 Wateridge Circle
San Diego, California 92121-2772

Re: K053049
Trade/Device Name: Alaris® Safety Male Luer
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 25, 2005
Received: October 28, 2005

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K053049 (To Be Assigned By FDA)

Device Trade Name:

Indications For Use:

The Safety Male Luer is indicated for use when reconstituting, dispensing/ transferring, administering, and disposal of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, as well as non-hazardous fluids. The Safety Male Luer is intended for use with the SmartSite® Needle Free Valve port or standard open female luers.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

Division of Cardiovascular Devices

K053049